

Dockets Management Branch
The Food and Drug Administration
Department of Health & Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Date: 8-30-99

Re: **99P-1340/CP 1** — Petition, to **Have Eternity eau de parfum declared "Misbranded"**

Dear Sir or Madam:

In May 1999, the Environmental Health Network (EHN) submitted the above petition to **have Calvin Klein's Eternity eau de parfum declared "misbranded."** I am writing because I fully support **this petition** and request that the FDA give it careful **attention with** regard to your regulations **21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10.** Regulation **21CFR Sec. 740.10** states;

- Each ingredient used in a cosmetic product and each finished cosmetic product **shall be adequately substantiated for safety prior to marketing.** Any such ingredient or product whose **safety** is not adequately **substantiated** prior to marketing is misbranded unless it contains the following **conspicuous statement** on the **principal display panel**:
- **"Warning — The safety of this product has not been determined."**

As the petition shows, Eternity contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all **have a right** to know. **the status** of safety testing of the ingredients in products **such as Eternity so that** we can protect ourselves and **our families** from **toxic chemicals that may** cause health problems. Most people are not aware. **that most** fragrance **materials have** only limited safety testing. They **wrongfully** assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people **with** asthma, chemical **sensitivities, chronic** fatigue, and other environmental illness? es. Children are particularly **vulnerable** to toxic **chemicals** found **in** products purchased **and** used by their parents, caregivers and teachers. **When I am** exposed to **fragrance products** I can experience any of the following symptoms **based upon the chemical** fragrance product I encounter:

- | | | | |
|---|---|--|---|
| <input checked="" type="checkbox"/> asthma | <input type="checkbox"/> double vision | <input checked="" type="checkbox"/> incoherence | <input checked="" type="checkbox"/> nausea |
| <input type="checkbox"/> anaphylaxis | <input type="checkbox"/> ear pain | <input type="checkbox"/> incontinence | <input type="checkbox"/> nose bleeds |
| <input checked="" type="checkbox"/> anxiety, restlessness | <input type="checkbox"/> eczema | <input checked="" type="checkbox"/> irritability | <input checked="" type="checkbox"/> rashes |
| <input checked="" type="checkbox"/> breathing difficulty | <input type="checkbox"/> eyes, watery or dry | <input type="checkbox"/> joint aches | <input type="checkbox"/> seizures |
| <input type="checkbox"/> bronchitis | <input checked="" type="checkbox"/> fatigue | <input type="checkbox"/> laryngitis | <input checked="" type="checkbox"/> short-term mem. loss |
| <input checked="" type="checkbox"/> can't concentrate | <input type="checkbox"/> flushing | <input checked="" type="checkbox"/> lethargy | <input type="checkbox"/> sinusitis |
| <input checked="" type="checkbox"/> coughing | <input checked="" type="checkbox"/> headaches | <input type="checkbox"/> lymph nodes swell | <input checked="" type="checkbox"/> sneezing |
| <input type="checkbox"/> depression | <input checked="" type="checkbox"/> heart beat irregularity | <input type="checkbox"/> mood swings | <input type="checkbox"/> sores, skin/mouth |
| <input checked="" type="checkbox"/> disorientation | <input checked="" type="checkbox"/> hives | <input checked="" type="checkbox"/> muscle pain/weakness | <input checked="" type="checkbox"/> swallowing difficulty |
| <input checked="" type="checkbox"/> dizziness | <input type="checkbox"/> hypertension | <input type="checkbox"/> nasal congestion | <input type="checkbox"/> tinnitus |
| <input type="checkbox"/> other: _____ | | | |

Please act **on** behalf of the **millions** of people who **have** suffered physical illness and **injury** resulting from fragrance exposure at work, at **school** and in social settings. These toxic chemicals act **as powerful barriers** to people disabled by asthma and **chemical** sensitivities. Toxic chemicals **in** fragrances **have already** ruined countless lives. Thank you.

Sincerely,

PATRICIA MAIKOSKI

your name

POB 12 Metamora, Mi. 48455

address; city/st/zip

99P-1340

Newsletters and everyone who feels people have a right to know, please copy, share, tell your friends and **WRITE the FDA... today!**

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tape shut

THE NEW REACTOR

May - June 1999